



**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D C 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

	EXAMINER
--	----------

ART UNIT	PAPER NUMBER
----------	--------------

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No. 09/451,641	Office Susan Tran	Gao et al. Art Unit 1615
-------------------------------	----------------------	--------------------------------

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on Jun 18, 2001
- 2a)  This action is FINAL.      2b)      This action is non-final.
- 3)      Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4)  Claim(s) 1-50 and 76-83 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)      Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-50 and 77-80 is/are rejected.
- 7)  Claim(s) 76 and 81-83 is/are objected to.
- 8)      Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9)      The specification is objected to by the Examiner.
- 10)     The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)     The proposed drawing correction filed on \_\_\_\_\_ is: a)      approved b)      disapproved.
- 12)     The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13)     Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a)      All b)      Some\* c)      None of:
1.      Certified copies of the priority documents have been received.
  2.      Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.      Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.

- 14)     Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- |   |   |
|---|---|
| 15)     Notice of References Cited (PTO-892)                        | 18)     Interview Summary (PTO-413, Paper No. s)        |
| 16)     Notice of Draftsperson's Patent Drawing Review (PTO-948)    | 19)     Notice of Informal Patent Application (PTO-152) |
| 17)     Information Disclosure Statement(s) (PTO-1449, Paper No. s) | 20)     Other   |

Art Unit: 1615

## DETAILED ACTION

Information Disclosure Statement filed 03/28/00, Extension of Time filed 04/06/00 and  
10/30/00, Declaration 04/06/00, Election filed 10/30/00, Amendment A filed 03/26/01, Request  
for Extension of Time filed 06/18/01, and Amendment B filed 06/18/01.

### *Claim Rejections - 35 U.S.C. § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all  
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black EP 0 863 134 ('134).

Black teaches a compound useful as a Cox-2 inhibitor for pain relief, fever and inflammation of a variety symptoms disclosed on page 3, lines 29-36. The compound can be administered orally in the form of tablets, troches, lozenges, or capsules (page 4, lines 1-12). The tablets comprising active ingredient in admixture with excipients, i.e. diluents, disintegrants, binding agents, wetting agents, and surfactant (page 4, lines 15-38). The active agent present in an amount of 10 to 250 mg, and carrier material may vary from about 5 to about 95% (page 5, lines 39-58). The dosage can be administered once or twice a day, and will provide effective T<sub>1/2</sub>

over a 24 hours period (page 5, lines 22-27). Example 2 discloses the amount of excipients use in a tablet.

The examiner notes that the reference is silent as to the teaching of celecoxib. However, it is the position of the examiner that celecoxib is one of the selective Cox-2 inhibitor and thus, it would have been *prima facie* obvious for one of the ordinary skill in this art to, by routine experimentation determine suitable Cox-2 inhibitor to treat cyclooxygenase-2 mediated diseases without any advert side effect to the gastrointestinal.

#### *Response to Arguments*

2. Applicant's arguments filed 06/18/01 have been fully considered but they are not persuasive. The Examiner maintains the above 103(a) rejection.

Applicant argues that Black does not teach a relative bioavailability not less than about 50%, by comparison with an orally delivered solution containing the same amount of celecoxib. However, applicant's specification page 48, lines 15-16 discloses, co-precipitating the celecoxib with a wetting agent (composition C) increased the bioavailability of celecoxib. Black teaches a compound useful as a Cox-2 inhibitor in the form of powders, granules, tablets, troches, suspensions, or emulsions for pain relief, fever and inflammation. The composition comprises carriers, diluents, excipients, surfactant, dispersing agent, and wetting agent in an amount falls within the claimed ranges. The composition is for controlled release, or sustained release having the claimed half-life, e.g., over 24 hour period. Accordingly, Black does recognize the use of

wetting agent in powder or granule formulation. Thus, it would have been obvious for one of the ordinary skill in this art to, by routine experimentation determine a suitable bioavailability rate of the compound useful as a Cox-2 inhibitor that is useful for the treatment of cyclooxygenase-2 mediated diseases without any advert side effect to the gastrointestinal. Furthermore, the burden is shifted to the applicant to establish that the powder or granule formulation of Black does not have the bioavailability rate of 50% or more.

#### *Allowable claims*

Claims 76, and 81-83 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1615

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 600 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*T. Tran*  
SUPERVISOR, M.P. DAWSON  
ART UNIT 162